

REMARKS

Claims 1-77 and 80 are pending in this application. None of the claims are amended, however, applicants herewith provide the pending claims for the examiner's convenience, which recite certain embodiments of the disclosure. The Office Action is discussed below:

Obviousness Rejection and the Response to Arguments:

On pages 2-8 of the Office Action, the examiner has maintained the obviousness rejection of the claims allegedly as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and further in view of Parth *et al.* (2002), and/or Burstein *et al.* (US 6,629,198), and/or Ylanen *et al.* (US 6,517,857).

On pages 8-9 of the Office Action, in response to the arguments, submitted September 29, 2006, the examiner states that Lidgren discloses a process for making crosslinked polymeric material by gamma irradiation and Hahn discloses a process for making a medical implant by either consolidating a polymeric material (UHMWPE) and doping said consolidated polymeric material with an antioxidant or, as an equivalent alternative, doping said polymeric material and then consolidating said doped, polymeric material (the examiner refers to Hahn's col. 3, lines 15-20 and col. 7, lines 24-47). The examiner believes that the process of Lidgren in view of Hahn's soaking of a consolidated polymeric material in an antioxidant solution renders the claimed invention obvious. Applicants respectfully disagree with the examiner, traverse the rejection, and reiterate that the art of the record does not teach or suggest, either alone or in combination, the formation of a "gradient of antioxidant in the consolidated polymeric material" (see pages 13-14 of the amendment filed September 29, 2006). Further, applicants specifically mention that Lidgren does not provide a gradient of antioxidant because Lidgren requires mixing of UHMWPE powder/particles with an antioxidant prior to consolidation (see page 14 of the amendment filed September 29, 2006).

Applicants reiterate that the examiner has not addressed the new and unexpected results of the instant methods, such as lower wear resistance, in the product, as compared to the Hahn and Lidgren processes.

Again, applicants submit that instantly claimed methods provide greater wear resistance to the medical implants because of increased cross-link density as compared to mixing a powder with vitamin E and then irradiating by Lidgren.

Example 4 of the captioned application concerns UHMWPE powder samples that were doped with Vitamin E prior to consolidation and irradiated with 100 kGy of gamma irradiation. Pin-on-disk wear testing showed that wear rate was reduced from the typical 8 mg per million cycles (no irradiation and no Vitamin E) to a range of 2 - 5 mg per million cycles, which is advantageous over conventional UHMWPE. Example 15, on the other hand, describes the irradiation (100 kGy gamma irradiation) and doping of consolidated UHMWPE with Vitamin E. As shown in Table 2, the pin-on-disk wear rate was reduced to 0.82 mg per million cycles when consolidated UHMWPE was doped, which is less than half the wear rate of the lowest end of the range from Example 4. Accordingly, applicants' approaches for doping consolidated UHMWPE, rather than UHMWPE powder, provide further significant wear resistance.

Accordingly, the claimed invention provides UHMWPE with new and unexpectedly advantageous properties, and therefore applicant's invention is not obvious as per the dictates of MPEP §2144(IV)(C). Accordingly, applicants respectfully request withdrawal of the obviousness rejection.

Although applicants submitted (see the response filed on September 29, 2006) that other cited references do not rectify the deficiencies of Lidgren in order to arrive at the claimed invention, the examiner asserts that these arguments merely attack references individually where the rejections are based on combinations of references. Again, applicants respectfully disagree with the examiner, and submit that the examiner is not considering the invention as a whole, and is using proscribed hindsight to reinterpret the teachings of the references.

Applicants further submit that the examiner has not addressed the issue that applicant raised in a response (filed July 6, 2005) to an earlier office action and that the examiner has not adequately explained the alleged motivation needed to establish a *prima facie* case of obviousness.

Applicants note that doping of consolidated UHMWPE by diffusion is nowhere suggested in Lidgren and on the other hand, Hahn also did not suggest crosslinking of the UHMWPE in order to obtain oxidation resistant medical implant. Moreover, the combination of Parth, Burstein, or Ylanen with Lidgren and Hahn is nowhere supported by the references or in the common knowledge of the art. Accordingly, the rejection calls to mind the Federal Circuit decision of *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), where the court explained:

As this court stated, “virtually all [inventions] are combinations of old elements.” *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); *see also Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) (“Most, if not all, inventions are combinations and mostly of old elements”). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an “illogical and inappropriate process by which to determine patentability.” *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Applicants submit that the rejection does not satisfy the strictures of the *Rouffet* decision. Because, the references are not combinable without proscribed hindsight.

Applicants also refer to MPEP and relevant case law and submit that:

“There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

“Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis). The teaching, suggestion, or motivation must be found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.”

See MPEP § 2143.01 (Rev. 5, August 2006 at 2100-127).

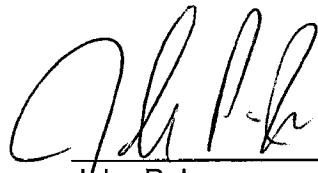
Therefore, the examiner has not established that alleged motivation to combine the cited references to arrive at the claimed invention, which is needed to establish a *prima facie* case of obviousness.

Withdrawal of the alleged obviousness rejection is therefore solicited.

REQUEST

Applicants submit that the claims 1-77 and 80 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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March 12, 2007

Date

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